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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,557	05/02/2002	Audrey Goddard	GNE.3230R1C39	9770

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EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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06/08/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/063,557

Applicant(s)

GODDARD ET AL.

Examiner

David J. Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/6/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claim 6 is cancelled.

Claims 1-5 are pending and under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

3. The rejection of claims 1-2 and 4-5 under 35 U.S.C. 102(a) as being anticipated by Lal et al (WO 00/00610, 1/6/2000, cited on PTO-892 mailed 4/15/2004) is withdrawn in view of applicants' arguments, the Declaration under 35 U.S.C 1.131 filed 10/14/2005 in view of *In re Moore* and *In re Stempel*.

Response to Arguments

4. The rejection of claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al (U.S. Patent 6,277,574 B1, 4/9/1999) is maintained.

The response filed 3/6/2007 as above that the previously submitted Declaration under 37 CFR 1.131 by Goddard et al filed 10/14/2005, which according to applicant establishes conception of the claimed invention prior to June 10, 1998 coupled with diligent reduction to practice. Since June 10, 1998 is prior to the effective date of the Walker et al reference (i.e., 4/9/1999), Applicant maintains that consistent with the decisions in *In re Moore* and *In re Stempel*, the Declaration under 37 CFR 1.131 submitted 10/14/2005 is sufficient to overcome the Walker reference. Applicants' arguments have fully been considered but are not found persuasive. While the examiner agrees that as in the cases of *In re Moore* and *In re Stempel* a Declaration under 37 CFR 1.131 by the applicant to swear behind a reference, which disclosed the claimed invention but did not provide a utility was sufficient to overcome the rejection. However, the facts in the instant case are distinguished from *In re Moore* and *In re Stempel* given the teachings of Walker et al. Walker et al teach a polypeptide sequence (SEQ ID NO:11; encoded by SEQ ID NO:5) that is identical to the claimed polypeptide

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sequence of SEQ ID NO:50 and antibodies thereto and the sequence of Walker is associated with kidney disease and is useful in the diagnosis, treatment and prognosis of diseases of the kidney (see entire document, particularly col. 11-14, 19, 22). Further, Walker et al claim the polynucleotide (i.e., SEQ ID NO:5), which encodes the polypeptide of SEQ ID NO:11, identical to the polypeptide claimed in the instant application. Thus, Walker et al disclosed the utility possessed by the polypeptide, which is more than what applicant has shown in US Provisional Application Serial No. 60/088,740, which is limited to the disclosure of the sequence of PRO1069. Applicant is reminded that under 37 CFR 1.131 practice, proof of a utility must be shown only if the reference discloses a utility. *In re Wilkinson*, 304 F.2d 673, 134 USPQ 171 (CCPA 1962); *In re Moore*, 444 F.2d 572, 170 USPQ 260 (CCPA1971).

The priority of the instant application is such that the earliest effective filing date is 8/24/2000, which is after the filing date of Walker et al. As discussed supra, the Declaration filed on 10/14/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the applied reference of Walker et al. The evidence submitted is insufficient to establish utility of the invention prior to the effective date of the Walker et al reference because the Declaration provides evidence that the differential expression of DNA59211-1450 (SEQ ID NO:49 encoding the claimed polypeptide SEQ ID NO:50) in various tumor samples, upon which applicant relies for utility and enablement of the claimed polypeptide (see utility and enablement rejections of record, particularly applicants' remarks thereto) was not established until the experiment performed on June 13, 2000.

Applicant is reminded that the prior-filed application must disclose the claimed invention of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112 for a benefit claim under 35 U.S.C. 120, 121, or 365(c), and also for a benefit claim under 35 U.S.C. 119(e).

For these reasons, the rejection of claims 1-2 and 4-5 under 35 U.S.C. 102(e) as being anticipated by Walker et al is maintained.

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5. The rejection of claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al (U.S. Patent 6,277,574 B1, 4/9/1999) in view of Queen et al (U.S. Patent 5,530,101, issued 6/96, cited previously on PTO-892 mailed 4/15/2004) is maintained.

Applicant argues as above for Walker, i.e., Applicants have demonstrated conception of the claimed invention prior to April 9, 1999 and diligence in reducing the invention to practice. Applicant concludes that Walker is not available as prior art. Applicants' arguments have fully been considered but are not found persuasive. The examiner's rebuttal above for Walker et al applies here as well and for these reasons the rejection is maintained. In response to applicant's arguments against the references individually, i.e., Queen et al do not teach antibodies which bind the polypeptide of SEQ ID NO:50, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is reiterated that Walker et al teach antibodies to the polypeptide of SEQ ID NO:11, which is identical to the claimed polypeptide of SEQ ID NO:50, wherein the antibodies are useful in the diagnosis, treatment and prognosis of diseases of the kidney and according to Queen et al humanized antibodies are less immunogenic in human patients compared to murine antibodies and hence, better suited for human therapy, Queen provides clear motivation for one of ordinary skill in the art to produce a humanized antibody against the polypeptide of SEQ ID NO:11 for therapeutic benefit in human kidney disease patients.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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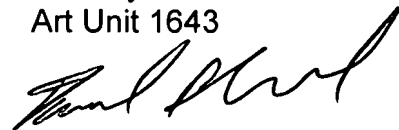
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Blanchard
Primary Examiner
Art Unit 1643



DB
May 23, 2007